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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/218,913	12/22/1998	RODERICK L. HALL	98.736	2461

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EXAMINER

NASHED, NASHAAT T

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/218,913	HALL ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14, and 16-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The application has been amended as requested in the communication filed March 31, 2004. Accordingly, new claims 19-29 have entered.

Claims 1-10, 14, and 16-29 are under consideration as they pertain to SEQ ID NO: 52.

The terminal disclaimer filed on December 10, 2004 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of a patent matured from copending U. S. application serial number 09/441,966 has been reviewed and is accepted. The terminal disclaimer has been recorded.

US patent 6,583,108 ('108) has been noted. Delaria *et al.* (J. Biol. Chem. 1997, 272 (18), 12209-12214) which is cited as prior art against the instant claims is a qualified prior art under 35 U. S. C. 102 (b), and it is utilized in rejecting the claims below. Delaria *et al.* teach the human placental bikunin of the '105 patent and has common authors with the '105 patent. The '105 patent is a qualified art against the instant claims under 35 U. S. C. 102(e), see the rejection below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-10, 14, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by U. S. Patent 6,583,108 (Tamburini *et al.*).

The '108 patent teaches the human bikunin of SEQ ID NO: 52, see the bottom of column 2. The human bikunin of SEQ ID NO: 52 is identical to that of SEQ ID NO: 52 of the instant application, and its use in the treatment of adult respiratory distress syndrome (ARDS) and emphysema (claims 1, 14, and 16-18), see column 15, second paragraph, and the last sentence of column 18. Also, it teaches that ARDS is characterized by pulmonary edema (excessive accumulation of fluids in the tissues) and

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decreased pulmonary compliance; see column 15, lines 6-11. Thus, the claimed method of increasing the mucociliary clearance is identical to method of treating ARDS (claims 1, 14, and 16-19). The '108 patent teach the formulation of the human bikunin into a pharmaceutical composition including aerosol and dry powder inhaler (claims 2-10 and 20-28), see from the second paragraph at column 20 through line 25 of column 21. In addition, the patent teaches the expression of SEQ ID NO: 52 in SF9 cells and characterization of a soluble placental bikunin which is glycosylated (claim 29), see example 9, starting at the bottom of column 45.

The following is a quotation of 35 U.S.C. 103, which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-10, 14, and 16-29 are rejected under 35 U.S.C. 103 as being unpatentable over Delaria *et al.* (J. Biol. Chem. 1997, 272 (18), 12209-12214) in view of the state of the art as exemplified by Rasche *et al.* [IDS, paper number 16, reference number 7, *Arzneimittel-Forschung* 25 (1) 110-116 (1975)], Fritz *et al.* (U. S. Patent 5,407,915), and O'Riordan *et al.* (IDS: Am. J. Respir. Crit. Care Med Vol. 155, pp. 1522-1528).

In response to the above rejections, Applicants continue to argue that the Office fails to establish a *prima facie* case of obviousness and continue to discredit each individual reference.

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Applicants' arguments filed 12/10/04 have been fully considered but they are not deemed to be persuasive. As indicated in the prior Office action, the cited prior art clearly contains all the teaching required to carry out the claimed invention including the amino acid sequence of SEQ ID NO: 52. Also, the prior art provides motivation to incorporate all the elements of the claimed invention. Fritz *et al.* motivate one of ordinary skill in the art to use human proteins having low molecular weight such as bikunin. Delaria *et al.* provide one of ordinary skill in the art with motivation to use the placental bikunin expressed in mammalian cells in the pharmaceutical composition as they teach a water-soluble glycosylated human bikunin. Rasche *et al.* teach a method of treating chronic bronchitis with Kunitz-type serine protease inhibitor, see above. O'Riordan *et al.* suggest that elastase inhibitor may be useful in protecting against mucociliary dysfunction, see page 41 of the response to the first Office action. Thus, the prior art provides the teaching to obtain the human bikunin of SEQ ID NO: 52, the motivation and expectation of success to use the human bikunin in the treatment of human disease such as ARDS, and, therefore, *prima facie* obviousness has been established.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner